StatSeal®

EXTRA SMALL TOPICAL DISC

StatSeal® is intended for use under the care of a healthcare professional for the temporary external control of bleeding from vascular access sites, and other procedures resulting in external bleeding. StatSeal can be used on all patient populations, regardless of age, gender, or ethnicity. Each application includes one (1) **StatSeal Extra Small Disc**.

INSTRUCTIONS FOR USE

1. Prepare skin around site per facility protocol.
2. Open sterile packaging and remove contents.
3. Place disc with label side up over site.
4. Maintain **continuous, semi-occlusive** pressure over disc for ≥ 2 minutes. Extend pressure times as clinically necessary.
5. Place transparent dressing per facility protocol. Apply product description label over dressing.
6. Leave disc in place until next scheduled dressing change.

SAFE DISPOSAL

StatSeal Devices must be disposed of in accordance with clinical waste laws applicable in the location of use.

INGREDIENTS: Hydrophilic polymer and potassium ferrate

PERFORMANCE CHARACTERISTICS: StatSeal Devices have a simultaneous two-step mechanism of action whereby the hydrophilic polymer rapidly dehydrates the blood and absorbs exudate, while the potassium ferrate binds with blood proteins to create an occlusive seal to stop the flow of blood. The blood seal is left on the wound site until it is naturally sloughed off as the permanent seal is produced by the natural forces of the body's repair mechanism.

CLINICAL BENEFITS: StatSeal Devices work independently of the clotting cascade to seal wounds and procedural sites, to stop external bleeding, and to reduce time to hemostasis.

DURATION OF CONTACT: StatSeal Devices are intended to be in contact with patient body for 30 days or less.

WARNINGS: FOR EXTERNAL USE ONLY. For single use only. Do not reuse. Reuse may compromise the sterility, safety and performance of the device. Not intended to replace stitches. Do not apply to visibly infected wounds. May be harmful if inhaled or ingested. Avoid aspirating product into the nasal or oral cavity. Avoid contact with eyes; if contact should occur, thoroughly rinse eyes with water. Depending on patient condition and amount of pressure application, the following may occur: vascular occlusion, hypodermic hematoma, continued bleeding, skin breakdown, discomfort, or numbness. Check hemostasis progress and adjust pressure as clinically necessary. Discontinue use if inflammation, irritation, tissue damage, or granulomatous reaction occurs. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

CAUTION: Store in a clean, dry place. Use by expiration date listed. Discard if product is damaged or opened. Discard contents after use. After opening, contents are no longer sterile.

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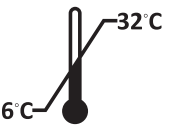
Symbols glossary: www.statseal.com/symbols



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